



Patient Information Sheet

Risperidone Tablets (marketed as Risperdal)

This is a summary of the most important information about Risperdal. For details, talk to your healthcare professional.

FDA ALERT [04/2005] –Risperdal is a type of medicine called an atypical antipsychotic. FDA has found that older patients treated with atypical antipsychotics for dementia had a higher chance for death than patients who did not take the medicine. This is not an approved use.

FDA has asked the companies that make these medicines to change their labels to include this important information.

This information reflects FDA's current analysis of all available data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

What is Risperdal?

- Risperdal is in a class of medications called atypical antipsychotics. Antipsychotic medicines are used to treat symptoms of schizophrenia that may include hearing voices, seeing things, or sensing things that are not there, mistaken beliefs or unusual suspiciousness.
- Risperdal may be used alone or with lithium or divalproex for short-term treatment of mixed or manic episodes in adults who have a condition called Bipolar I disorder. Bipolar disorder is a mental illness that causes extreme mood swings.

What are The Risks?

The following are the major potential risks and side effects of Risperdal therapy. However, this list is not complete.

Risperdal and other antipsychotic medications can cause serious problems such as:

- **A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- **A movement problem called tardive dyskinesia (TD).** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- **High blood sugar and diabetes.** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.

- **Strokes** have happened in older patients treated for mental illness from dementia. Risperdal is not approved for this use. See FDA Alert.
- **Other serious side effects** may include low blood pressure seen as dizziness, increased heart beat and possibly fainting, seizures, persistent erection, thrombotic thrombocytopenic purpura (seen as fever and bruising), increase or decrease in body temperature, and difficulty swallowing.
- **The most common side effects** include anxiety, uncontrolled movements, constipation, nausea, upset stomach, runny nose, rash, vision changes, saliva increase, abdominal pain, inability to control urination, weight gain.

What Should I Tell My Healthcare Professional?

Before you start taking Risperdal, tell your healthcare professional if you:

- have or had heart problems
- have or have had seizures.
- have or had diabetes or increased blood sugar
- have or had liver disease
- have an obstruction of your intestines
- have Reye's syndrome
- have a brain tumor
- are trying to become pregnant, are already pregnant, or are breast-feeding.
- drink alcohol
- have a condition called phenylketonuria

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with Risperdal, review all medications that you are taking with your healthcare professional, including those that you take without a prescription.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following medications:

- blood pressure medicines
- levodopa and medicines called dopamine agonists
- clozapine
- carbamazepine
- phenytoin
- rifampin
- phenobarbital
- fluoxetine and paroxetine





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Avoid drinking alcohol while taking Risperdal.

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Is There Anything Else I Need to Know?

- Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with Risperdal, especially when you first start taking this medicine or when the dose is increased.
- Risperdal may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how Risperdal affects you.
- It is important to avoid overheating and dehydration while taking Risperdal. Risperdal may make it harder to lower your body temperature.



Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
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